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REMARKS

Claims 21 and 30-44 are pending and under consideration.

Claim 21 has been amended.

Claim Amendments

Claim 21 has been amended to recite that the TLR8 agonist comprises a 2-aminopyridine fused to a five membered nitrogen-containing heterocyclic ring in an amount effective to modulate at least one TLR8-mediated cellular signaling pathway. Support for the amendment can be found throughout the application such as at, for example, page 15, lines 26 and 27, and page 2, lines 1-21. No new matter is introduced by this amendment.

§ 112 Rejections

§112, first paragraph, Written Description

Claims 21 and 30-44 stand rejected under 35 USC §112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the entire scope of the claimed subject matter. Specifically, the Office Action notes that the claim is not defined by any structural limitations.

Claim 21 has been amended to recite specific structural limitations defining the claimed genus of TLR8 agonists, thereby obviating the rejection.

§112, first paragraph, Enablement

Claims 21 and 30-44 stand rejected under 35 USC §112, first paragraph, as failing to reasonably provide enablement for any or all TLR8 agonists recited in claim 21. The Office Action cites the factors enumerated in *In re Wands* to be considered when determining whether a disclosure satisfies the enablement requirement. The Office Action specifically cites the amount of experimentation and the unpredictability of the art as factors that weigh against Applicants' disclosure enabling the full scope of the claimed subject matter.

Claim 21 has been amended to recite the core chemical structure that defines compounds encompassed within the scope of the claims. Each of the more than 60 specific TLR8 agonist compounds identified in Applicants' specification (see, e.g., Tables 1-3 and Figures 1-11) falls within the scope of claim 21, as amended. With the recitation of chemical structure in claim 21, one skilled in the art would require no experimentation to determine whether a particular compound is encompassed by the structural scope of claim 21.

Applicants further submit that any experimentation needed to determine whether a particular compound possesses TLR8 agonist activity is not undue, but is minimal and routine. In *In re Wands*, the Federal Circuit held that performing ELISAs—known, routine immunoassays—on hybridoma cultures *in vitro* to identify those that make a particular monoclonal antibody was not undue experimentation. Applicants describe in Example 5 a routine experiment employing only known methods for identifying compounds that induce a dose-dependent TLR8-mediated cellular response *in vitro*. This method requires no more—and arguably even less—experimentation that that required in *In re Wands*. Because it requires no more experimentation than that which the Federal Circuit has determined to be permissible for the purposes of determining enablement, Applicants' disclosure enables the full scope of the claims, as amended.

Finally, the Office Action asserts the "high degree of unpredictability" in the art, but provides no relevant support for that conclusion. The Office Action questions whether "all proteins belonging to the TLR8 family would be an agonist or that all agonist [sic] of the TLR8 family of proteins would function as desired in the pharmaceutical composition."

Applicants' disclosure makes no assertion that proteins belonging to the TLR8 family would be agonists, nor do Applicants claim proteins of the TLR8 family as agonists. Proteins of the TLR8 family are the receptors that are activated by compounds recited in Applicants' claims.

Applicants' disclosure provides ample disclosure regarding the amount of TLR8 agonist needed to function as desired in a pharmaceutical composition. Such disclosure is found, for example, from page 23, line 29 through page 24, line 28, and in Examples 2-4 (Figs. 1-6).

Applicants therefore submit that the full scope of the claims, as amended herein, is enabled by Applicants' disclosure.

In summary, Applicants submit that claims 21 and 30-44 meet the requirements of 35 USC §112, first paragraph, and that the rejections should be withdrawn.

§112, second paragraph.

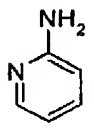
Claims 21 and 30-44 stand rejected under 35 U.S.C. §112, second paragraph, as failing to set forth the subject matter that Applicants regard as their invention. Specifically, the Office Action asserts that the claims recite a laundry list of compounds and that it is unclear how the compounds are associated. Applicants respectfully traverse.

Applicants respectfully submit that one skilled in the art recognizes the structural relationship among the classes of compounds recited in claim 21. That structural relationship is expressly recited in claim 21: a 2-aminopyridine fused to a five membered nitrogen-containing heterocyclic ring, and otherwise provided in Applicants' disclosure (e.g., page 15, lines 26 and 27). A recitation of immunostimulatory compound classes that share the very same structural core—e.g., a 2-aminopyridine fused to a five membered nitrogen-containing heterocyclic ring—as the compounds recited in claim 21 have been deemed to be definite in issued U.S. Pat. No. 7,179,253 (*see*, col. 6, lines 11-50), even without the generic structural language added to claim 21 herein.

Thus, Applicants submit that claims 21 and 30-44 meet the requirements of 35 U.S.C. §112, second paragraph and respectfully request that the rejection be withdrawn.

§ 102 Rejections

Claims 21 and 30 stand rejected under 35 USC §102(b) as being anticipated by Richardson (*J. Org. Chem.*, 1963, vol. 25, p. 1138). Claim 21 has been amended to recite a 2-aminopyridine fused to a five membered nitrogen-containing heterocyclic ring. The structure of 2-aminopyridine is shown below.



The compounds disclosed by Richardson do not include a pyridine ring. Therefore, Richardson cannot possibly disclose compounds having a 2-aminopyridine ring, much less the 2-aminopyridine ring fused to a five membered nitrogen-containing heterocyclic ring recited in the claims.

Applicants submit that claims 21 and 30 are novel over Richardson and, therefore, satisfy the requirements of 35 USC §102(b). Applicants respectfully request that the rejection be withdrawn.

Double Patenting Rejection

Claim 1 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting. Claim 1 is canceled, rendering the provisional double patenting rejection moot.

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CONCLUSION

In view of the above, it is submitted that the application is in condition for allowance.

Reconsideration of the application is requested.

Allowance of claims 21 and 30-44, as amended, at an early date is solicited.

Respectfully submitted
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May 24, 2007
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CERTIFICATE UNDER 37 CFR §1.8:
The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 24th day of May, 2007, at 3:42 pm (Central Time).

By: Danielle Moore
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